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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,923	SAVIO ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. The Applicants' response to the office action mailed on 9/12/2006, including arguments/remarks, and amendments to the claims and specification, was received on 1/16/2007 and has been entered into the record.

2. The Applicants have cancelled claims 1-13, and have added new claims 14-22, which are currently pending and the subject of this office action.

Specification

Objection to the specification, regarding improperly identified trademarks, as set forth on page 2 of the office action mailed on 9/12/2006, is *withdrawn* in response to Applicants' amendments to the specification to identity the trademark SUPERDEX.

Claim Objections

1. The Examiner suggests the syntax of claims 16, 17, and 20 can be improved by amending the claims to read "wherein the method comprises administering....."

2. The Examiner suggests the syntax of claim 22 can be improved by amending the claim from "autologous IL-15 comprising administering to a host.....", to "autologous IL-15, wherein said method comprises administering to a host...."

3. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, independent claim 14 recites a composition wherein IL-15 is an antigen, and dependent claim 15 recites the composition of claim 14 wherein IL-15 is recombinant protein obtained in E. coli, and wherein the IL-15 has a

glycosylation pattern different from autologous IL-15. Claim 15 does not further limit the subject matter of claim 14 because both claims are drawn to a composition comprised of IL-15. The recombinant IL-15 recited in claim 15 would perform the same role or function as the IL-15 of claim 14, and additionally, would have the same sequence and structure, unless Applicants can provide evidence to the contrary.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19 and 21 are *rejected* under 35 U.S.C. 101, as originally applied to claims 8-12 on page 4 of the office action mailed on 9/12/2006, because the claimed invention is directed to non-statutory subject matter. The claims are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153, USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). This rejection may be obviated by amending the claim to read "administered" instead of "used".

Claim Rejections - 35 USC § 112, first paragraph – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 16-22 are *rejected* under 35 USC § 112, first paragraph, regarding lack of enablement for methods of treating an "IL-15 expression-related disorder by administration of a composition comprising human IL-15 for generating neutralizing antibodies in humans, as originally applied to claims 5-13 on pages 4-5 of the prior office action mailed on 9/12/2006.

The claims of the instant invention are drawn to methods of treating an "IL-15 expression-related disease" by administering a composition comprising human IL-15, and specifically human IL-15. In the response received on 1/16/2007, the Applicants argue that the

specification shows proof of concept by showing that administration of human IL-15 to monkeys generates neutralizing anti-IL-15 antibodies. The Applicants also argue that tolerance to human IL-15 can be disrupted in humans because the human and simian IL-15 polypeptide amino acid sequences are 97% homologous, and furthermore, the Applicants have observed recognition of peptides with sequences identical to simian IL-15, which suggests immunological tolerance can be disrupted. For these reasons, the Applicants assert that the specification is enabling for a composition comprising human IL-15 for generating neutralizing anti-IL-15 antibodies in humans, and methods of treating an "IL-15 expression-related disease" in humans by administration of said composition.

These results have been fully considered and are not persuasive. As stated in the previous office action mailed on 9/12/2006, the breadth of the claims is excessive because they are drawn to methods of treating any "IL-15 expression-related disease", including leukemia and all possible autoimmune diseases. Given the broadest reasonable interpretation, the claims can be considered to read on the treatment of any disease in which IL-15 is expressed. There is no guidance or examples in the specification that shows that any "IL-15 expression-related disease", such as leukemia or any autoimmune disease, can be effectively treated by administration of a composition comprising IL-15, wherein said composition induces the generation of neutralizing antibodies against autologous IL-15. Given the wide range of etiology and pathology involved with all possible "IL-15 expression-related diseases", including all possible autoimmune diseases, one of ordinary skill in the art would not be able to predict which of many possible diseases which is IL-15 "expression-related", including all possible autoimmune diseases, could be treated by the claimed method. Furthermore, although administration of the claimed composition comprised of human IL-15 may induce neutralizing antibodies against autologous IL-15 in humans, one of ordinary skill in the art would also suspect, in absence of evidence to the contrary, that administration of a composition comprising IL-15 would *exacerbate*, and not treat, most IL-15 expression-related disorders. Because of this unpredictability, one of ordinary skill in the art would require further, undue experimentation in order to practice a method of treating any "IL-15 expression-related disorder" by administration of a composition comprising IL-15 as an antigen.

2. Claims 19 and 21 are *rejected* under 35 USC § 112, first paragraph, regarding lack of enablement for methods of treating an "IL-15 expression-related disorder by administration of a

composition comprising human IL-15 for generating neutralizing antibodies in humans, wherein said composition is used concurrently with an anti-inflammatory drug or a cytokine antagonist, as originally applied to claims 8 and 13 on pages 5-6 of the prior office action mailed on 9/12/2006.

The subject matter of the claims of the instant invention is discussed supra. Claims 19 and 21 are further drawn to methods of treating disease by administration of a composition comprising IL-15, wherein said composition is used concurrently with an anti-inflammatory drug or cytokine antagonist.

In the reply received on 1/16/2007, the Applicants argue that anti-inflammatory drugs and cytokine antagonists would be known to a skilled artisan. This argument has been fully considered and is not persuasive. The claims read broadly on an undefined, concurrent use of any anti-inflammatory drug, or an antagonist of any cytokine. Furthermore, the claims do not specify that the anti-inflammatory drug or cytokine antagonist be used for treatment of any disease. Assuming that the intended use of the anti-inflammatory drug or cytokine antagonist is in the treatment of a disease, a skilled artisan still would not be able to predict the effect of using all possible cytokine antagonists for treatment of autoimmune disease or leukemia. For example, would an antagonist of IL-4 be effective in treating all possible autoimmune diseases when used concurrently with the claimed composition? The specification does not provide any guidance or examples that would teach a skilled artisan which cytokine antagonists could be used in the manner set forth in the claims, and due to the well-known complexity of various autoimmune diseases, one of ordinary skill in the art would not be able to predict how to use all possible cytokine antagonists without further, undue experimentation.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 19 and 21 are *rejected* under 35 USC § 112, second paragraph, as originally applied to claims 8-13 on pages 7-8 of the office action mailed on 9/12/2006. Claims 19 and 21 provide for the concurrent use of an anti-inflammatory drug or cytokine antagonist, but since the claims do not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

2. Original claims 1-13 were rejected under 35 USC § 112, second paragraph, as being indefinite regarding the metes and bounds of "human IL-15", as set forth on page 7 of the office action mailed on 9/12/2006. In the response received on 1/16/2007, the Applicants argue that the specification clearly intends that the "IL-15" claimed was obtained by a process using E. coli, and therefore the obtained IL-15 has the same amino acid sequence as mature human IL-15. This argument has been considered and is persuasive, and therefore the original rejection applied to claims 1-13 is not applied to the currently pending claims 14-22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 14 is *rejected* under 35 USC § 102(b) as being anticipated by Grabstein *et al* (US 6,013,480), as originally applied to claims 1-2 on page 8 of the office action mailed on 9/12/2006. In the reply received on 1/16/2007, the Applicants argue that the claims are now amended to recite a composition for generating neutralizing self-antibodies against autologous IL-15, wherein the composition comprises IL-15 as an antigen. The Applicants assert that the '480 patent does not teach a composition that generates self-antibodies against autologous IL-15, and therefore the '480 patent does not anticipate the limitations of the currently pending claims.

These arguments have been fully considered and are not persuasive. As stated in the previous office action, the '480 patent teaches a composition comprised of IL-15. Although the '480 patent does not specifically recite a composition comprised of IL-15 that generates self-antibodies to autologous IL-15, it would be expected, in the absence of evidence to the contrary, that the composition of the '480 patent would indeed generate self-antibodies against

autologous IL-15 when administered to a human because the composition of the '480 patent is comprised of human IL-15 in a vaccine composition. The USPTO does not have the facilities for testing the IL-15 composition of the '480 patent, and therefore burden is on the Applicants to show a novel and unobvious difference between the claimed composition and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the disclosure of the '480 patent meets the limitations of claim 14 of the instant application.

2. Claims 14, 16, and 22 are *rejected* under 35 USC § 102(a) as being anticipated by Grooten *et al* (US 6,344,192), as originally applied to claims 1-2, 5-7, and 9-11 on pages 8-9 of the office action mailed on 9/12/2006. In the reply received on 1/16/2007, the Applicants argue that the claims are now amended to recite a composition for generating neutralizing self-antibodies against autologous IL-15, wherein the composition comprises IL-15 as an antigen. The Applicants assert that the '192 patent does not teach a composition that generates self-antibodies against autologous IL-15, and therefore the '192 patent does not anticipate the limitations of the currently pending claims.

These arguments have been fully considered and are not persuasive. As stated in the previous office action, the '192 patent teaches a composition comprised of IL-15. Although the '192 patent does not specifically recite a composition comprised of IL-15 that generates self-antibodies to autologous IL-15, it would be expected, in the absence of evidence to the contrary, that the composition of the '192 patent would indeed generate self-antibodies against autologous IL-15 when administered to a human. Because the USPTO does not have the facilities for testing the IL-15 composition of the '192 patent, the burden is on the Applicants to show a novel and unobvious difference between the claimed composition and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the disclosure of the '192 patent meets the limitations of claim 14 of the instant application.

Furthermore, as set forth on page 9 of the office action mailed on 9/12/2006, the '192 patent teaches administration of the IL-15 comprising composition to individuals. Although the '192 patent does not specifically recite treatment of an "IL-15 expression-related disease", it is noted that given the broadest reasonable interpretation, an "IL-15 expression-related disease can be any disease characterized by IL-15 expression, whether it be increased or decreased

expression. Furthermore, the method steps of administration of the composition of the '192 patent do not differ from the method steps of administering the composition of the instant invention, and there is nothing that separates the population of the '192 patent from that of the instant application. Therefore, because the '192 patent discloses a composition comprise of IL-15, which is the same as the composition of the instant application and would be expected to generage neutralizing antibodies when administered to a human, and the method of administration of the IL-15 comprising composition taught by the '192 patent are not distinct from those of the instant application, the disclosure of the '192 patent meets the limitations of claims 16 and 22 of the instant application, regardless of the intended use of either composition (*Ex parte* Novitski, 26 USPQ 1391).

3. Claims 14-16 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Grabstein *et al* (WO 95/27722). The subject matter of the claims of the instant invention is discussed *supra*. Claim 15 is further drawn to a composition comprising IL-15, wherein the IL-15 is a recombinant protein produced in *E. coli*, and wherein said IL-15 has a glycosylation pattern different from autologous IL-15.

Grabstein *et al* teaches isolation and cloning of human IL-15, and specifically teaches that IL-15 can be recombinantly produced in *E. coli* (see page 12, lines 3-14, and claims 1-9). Grabstein *et al* also teaches that native glycosylation patters are achieved by expression in mammalian cells, while IL-15 expressed in prokaryotes (i.e. *E. coli*), is not glycosylated (page 6, lines 2-4). Also taught by Grabstein *et al* are pharmaceutical compositions of recombinantly produced IL-15, and methods of administering said IL-15 to patients (see page 15, line 24 – page 16, line 2). Therefore, because Grabstein *et al* teaches a pharmaceutical composition comprising recombinant IL-15 produced in *E. coli*, and because this IL-15, by virtue of being non-glycosylated, would have different glycosylation from autologous IL-15. Although the Grabstein *et al* does not specifically recite a composition comprised of IL-15 that generates self-antibodies to autologous IL-15, it would be expected, in the absence of evidence to the contrary, that the composition of the Grabstein *et al* would indeed generate self-antibodies against autologous IL-15 when administered to a human. The USPTO does not have the facilities for testing the IL-15 composition of Grabstein *et al*, and therefore burden is on the Applicants to show a novel and unobvious difference between the claimed composition and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ

2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the disclosure of Grabstein *et al* meets the limitations of claims 14-15 of the instant application.

Furthermore, Grabstein *et al* teaches administration of IL-15 comprising compositions to individuals (page 15, line 24 – page 16, line 2). Although Grabstein *et al* does not specifically recite treatment of an "IL-15 expression-related disease", it is noted that given the broadest reasonable interpretation, an "IL-15 expression-related disease" can be any disease characterized by IL-15 expression, whether it be increased or decreased expression. Furthermore, the method steps of administration of the composition of Grabstein *et al* do not differ from the method steps of administering the composition of the instant invention. Additionally, there is nothing that separates the population of Grabstein *et al* from that of the instant application. Therefore, because Grabstein *et al* discloses a composition comprise of IL-15, which is the same as the composition of the instant application and would be expected to generate neutralizing antibodies when administered to a human, and the method of administration of the IL-15 comprising composition taught by Grabstein *et al* are not distinct from those of the instant application, the disclosure of Grabstein *et al* meets the limitations of claims 16 and 22 of the instant application, regardless of the intended use of either composition (*Ex parte* Novitski, 26 USPQ 1391).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 14-22 are *rejected* under 35 USC § 103(a) as being anticipated by the combination of Grabstein *et al* (US 6,013,480 – "the '480 patent") and Gonzalez *et al*, as originally applied to claims 3-13 on pages 9-11 of the office action mailed on 9/12/2006, and further in view of Grabstein *et al* (WO 95/27722 – "the '722 document"). The subject matter of the claims of the instant invention, and the disclosure of the '480 patent and the '722 document, is discussed *supra*. Claims 19 and 21 are further drawn to methods of treatment comprising administering an IL-15 comprising composition, wherein said composition is used concurrently

with an anti-inflammatory drug or cytokine antagonist. In the reply received on 1/16/2007, the Applicants argue that the claims are now amended to recite a composition for generating neutralizing self-antibodies against autologous IL-15, wherein the composition comprises IL-15 as an antigen. The Applicants assert that the '480 patent does not teach a composition that generates self-antibodies against autologous IL-15, and therefore the claims of the instant invention are not obvious in view of any combination based on the '480 patent.

These arguments have been fully considered and are not persuasive. As set forth *supra*, the '480 patent and the '722 document both disclose composition comprising IL-15, including recombinant IL-15 produced in *E. coli* ('722). Furthermore, as set forth *supra*, it would be expected, in absence of evidence to the contrary, that the compositions of either the '480 patent or the '722 document would be capable of generating neutralizing self-antibodies against autologous IL-15. In addition, the '480 patent teaches that IL-15 antagonists are useful for treating diseases such as leukemia, rheumatoid arthritis, and inflammatory bowel disease. Gonzalez teaches a method of coupling a carrier protein to a polypeptide in order to increase the immunogenicity of said polypeptide.

Therefore, one of ordinary skill in the art would be motivated to practice the instant invention by following the combined teachings of the '480 patent, the '722 document, and Gonzalez. The motivation to do so comes from the disclosures of the '480 patent and the '722 document which teach IL-15 comprising compositions which would be expected to generate neutralizing self-antibodies against autologous IL-15, and the teachings of Gonzalez which teach a method to further increase the immunogenicity of IL-15. One of ordinary skill in the art would also recognize that neutralizing antibodies against IL-15 are IL-15 antagonists, and the '480 patent teaches that IL-15 antagonists are useful for treating the claimed diseases. Thus, a skilled artisan would be motivated to administer the composition of the '480 patent or the '722 document, wherein the IL-15 is conjugated as set forth in Gonzalez, to an individual in order to generate neutralizing self-antibodies against autologous IL-15 for treatment of autoimmune diseases such as rheumatoid arthritis, or leukemia. Furthermore, although the cited references do not specifically recite concurrent use with an anti-inflammatory drug or a cytokine antagonist, it is noted that the claims do not specifically set forth a "use" for these agents. It is also noted that anti-inflammatory drugs are well-known in the art, as evidenced by the Applicants' statement on page 7 of the response received on 1/16/2007. Therefore, it would also be

obvious to one of ordinary skill in the art to concurrently use an anti-inflammatory drug with the composition of the instant invention.

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

ROBERT S LANDSMAN, PH.DD.
PRIMARY EXAMINER